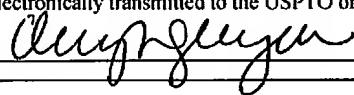


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Date: January 20, 2011

Signature:



(Quyen Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/797,485

Confirmation No.: 3298

Filing Date: March 9, 2004

Inventor(s): Vahid SAADAT et al.

Title: ENDOLUMINAL TOOL DEPLOYMENT SYSTEM

Examiner: Matthew J. Kasztejna

Group Art Unit: 3739

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**APPEAL BRIEF**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief for the above-identified application in which pending claims 67-71, 73, 74, 76-80, 82-84, 92, and 94-96 were rejected in a Final Office Action mailed February 23, 2010 ("the Office Action").

A Notice of Appeal was filed in this case on August 20, 2010. The fees required for filing this Appeal Brief are transmitted herewith. The Commissioner is authorized to charge **Deposit Account No. 50-3973** for any other fees that may be due with this Appeal referencing Attorney Docket No. USGINZ00130.

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**I. REAL PARTY IN INTEREST**

The Application is assigned to USGI Medical Inc., a Delaware Corporation having its principal place of business at 1140 Calle Cordillera, San Clemente, California 92673.

**II. RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

**III. STATUS OF THE CLAIMS**

Claims 67-71, 73, 74, 76-80, 82-84, 92, and 94-96 were finally rejected and are the subject of this Appeal. Claims 1-66, 72, 75, 81, 85-91, and 93 were cancelled.

**IV. STATUS OF AMENDMENTS**

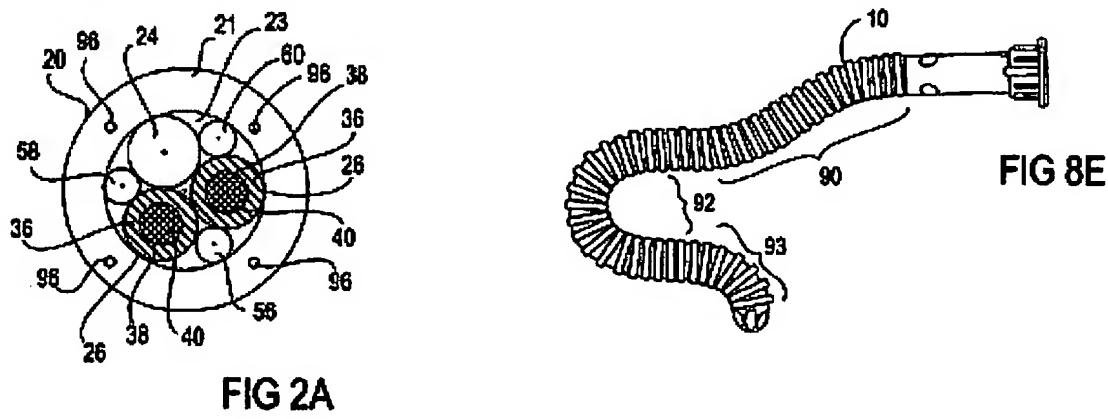
No amendments were filed subsequent to final rejection of the claims.

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

A summary of independent claims, as well as those dependent claims to which separate arguments are being presented, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting list of locations where support may be found [bracketed citations] is provided as follows:

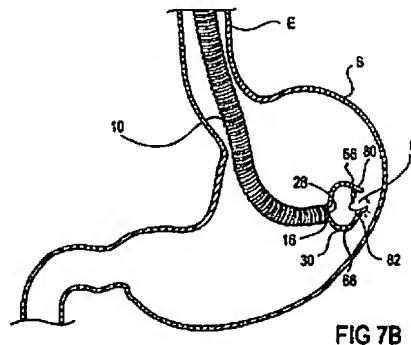
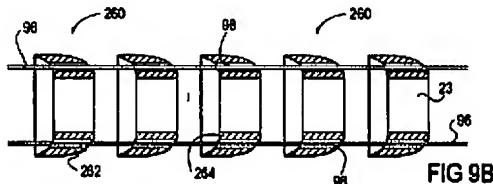
The claims on appeal describe an endoscopic apparatus that is used, for example, to access and manipulate tissue in the body of a patient via a natural body orifice or a laparoscopic port. Embodiments of the apparatus include an elongated main body having first and second independently shape-lockable and/or steerable sections and a variety of instruments that are either built into the main body or that are advanceable through lumens that extend through the main body. The ability to steer and shape-lock specific sections of the main body enables access to target locations within the body of the patient that are typically challenging to reach and provides a stabilized platform to perform a desired procedure at the target location.

Exemplary embodiments of the endoscopic apparatus are shown in the figures reproduced below. The apparatus includes an elongated main body 10 having a shaft 20 defining a central lumen 23, and a plurality of lumens 24, 26, 28 extending through the central lumen 23 (see FIG. 2A). The shaft 20 is a single tube that may include first,



second, and third longitudinal sections 90, 92, 93 (see FIG. 8E). In an embodiment, the first section 90 is flexible, the second section 92 is shape-lockable, and the third section 93 is steerable relative to the second section 92. One or more sections of the shaft 20

may incorporate a plurality of nested links 260 (see FIG. 9B), which include pullwires 96 extending through pullwire lumens 98. The pullwires 96 are used to hold the elements



260 in a nested alignment and to provide steering and locking. In FIG. 7B, an apparatus 10 is shown advanced through the esophagus E and into the stomach S of the patient. The distal section is steered to a target location where tool arms 30 carrying tools 40 are advanced through lumens of the main body. For example, an endoscope 28 may be advanced through the endoscope lumen 26 to exit at the distal end of the main body.

Turning to the specific claims, claim 67 describes an endoluminal apparatus. [Paragraph 0014, lines 1-10; Paragraph 0074, lines 1-16; FIGS. 7A-B]. The apparatus includes an elongated main body (10) having a proximal end (12), a distal end (14), a longitudinal axis, and at least one lumen (24, 26, 28) extending through the main body. [Paragraph 0063, lines 1-6; Paragraph 0064, lines 1-9; Paragraph 0070, lines 1-6; FIGS. 1, 2, 2A-B]. The main body comprises a single tube (20). [Paragraph 0069, lines 1-7; FIGS. 2A-B]. A first section (90) of the main body near the proximal end comprises a plurality of nested links (260) with substantially all adjacent links having mating surfaces (262, 264) that are in contact with but that are not connected to each other. [Paragraph 0080, lines 7-12; Paragraph 0088, lines 1-5; FIGS. 8A-E, 9A-B]. Each of the nested links (260) includes a plurality of first pullwire lumens (98). [Paragraph 0088, lines 5-7; FIGS. 9A-B].

A plurality first pullwires (96) are routed through substantially each of the first pullwire lumens (98). [Paragraph 0088, lines 5-13; FIGS. 9A-B]. Each of the first pullwires (96) is fixed to the elongated main body at a location at or near a distal end of

the first section and a substantially a common point along the longitudinal axis of the main body. [Paragraph 0089, lines 1-7]. The first pullwires (96) are substantially symmetrically spaced around the periphery of the nested links (260) of the first section (90). [Paragraph 0090, lines 4-6; FIG. 9C].

A tensioning mechanism is operatively coupled to each of the first pullwires (96). [Paragraph 0122, lines 1-10; Paragraph 0123, lines 1-5; FIGS. 19A-D]. The tensioning mechanism is adapted to impart a tension force that is substantially evenly distributed to each of the first pullwires, such that the first section of the main body may be selectively switched between a substantially flexible condition and a substantially rigid condition. [Paragraph 0122, lines 3-6; Paragraph 0124, lines 1-3; FIGS. 19A-D].

A second section (92) of the elongated main body is located near the distal end and is steerable relative to the first section (90). [Paragraph 0080, lines 8-16; FIGS. 8A-C].

A scope (28) extends through at least a portion of the lumen (24) of the elongated main body. [Paragraph 0071, lines 14-15; Paragraph 0073, lines 8-13; Paragraph 0074, lines 6-7; FIGS. 6, 7A-B]. The scope is moveable through the lumen relative to the elongated main body. [Paragraph 0071, lines 14-15; Paragraph 0073, lines 8-13; Paragraph 0074, lines 6-7; FIGS. 6, 7A-B].

Claim 92 describes an apparatus that includes a shaft (10) having a first section (90), a second section (92), and a longitudinal axis. [Paragraph 0080, lines 7-12; FIGS. 8A-C]. The shaft (10) comprises a single tube (20). [Paragraph 0069, lines 1-7; FIGS. 2A-B]. The first section (90) of the shaft includes a plurality of first links (260), with substantially all adjacent links pivotably abutting each other but not connected to each other, and with each first link having a contoured front surface (262) adapted to engage with a contoured back surface (264) of an adjacent first link. [Paragraph 0080, lines 7-12; Paragraph 0088, lines 1-5; FIGS. 8A-E, 9A-B]. Each of the nested links (260) includes a plurality of first pullwire lumens (98). [Paragraph 0088, lines 5-7; FIGS. 9A-B].

A plurality first pullwires (96) extend through substantially each of the first pullwire lumens (98). [Paragraph 0088, lines 5-13; FIGS. 9A-B]. Each of the first pullwires (96) is fixed to the shaft at a location at or near a distal end of the first section

and a substantially a common point along the longitudinal axis of the main body. [Paragraph 0089, lines 1-7]. The first pullwires (96) are substantially symmetrically spaced around the periphery of the first links (260) of the first section (90). [Paragraph 0090, lines 4-6; FIG. 9C].

The second section (92) of the shaft includes a plurality of second links (260), with substantially all adjacent second links pivotably abutting each other but not connected to each other, and with each second link having a contoured front surface (262) adapted to engage with a contoured back surface (264) of an adjacent second link. [Paragraph 0080, lines 7-12; Paragraph 0088, lines 1-5; FIGS. 8A-E, 9A-B].

At least one second section steering wire (96) extends through substantially each of the first links and the second links. [Paragraph 0091, lines 1-6; FIG. 9D].

At least one working lumen (24) extends through substantially each of the first links and the second links. [Paragraph 0093, lines 8-10; FIG. 9E].

A scope (28) extends through at least a portion of the lumen (24) of the shaft. [Paragraph 0071, lines 14-15; Paragraph 0073, lines 8-13; Paragraph 0074, lines 6-7; FIGS. 6, 7A-B]. The scope is moveable through the working lumen relative to the shaft. [Paragraph 0071, lines 14-15; Paragraph 0073, lines 8-13; Paragraph 0074, lines 6-7; FIGS. 6, 7A-B].

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 67-71, 73-74, 76-80, 82-83, and 95-96 are patentable under 35 U.S.C. § 102(b) over U.S. Patent No. 5,251,611 to Zehel et al. (hereinafter "Zehel").
2. Whether claims 84 and 94 are patentable under 35 U.S.C. § 103(a) over Zehel in view of U.S. Patent No. 3,897,775 to Furihata ("Furihata") (as to claim 84), or Zehel in view of U.S. Patent No. 5,916,147 to Boury ("Boury") (as to claim 94).
3. Whether claim 92 is patentable under 35 U.S.C. § 103(a) over Zehel in view of Boury.

## VII. ARGUMENT

Appellants respectfully submit that claims 67-71, 73, 74, 76-80, 82-84, 92, and 94-96 are in proper form and are patentable over the prior art of record. Appellants request that the Board overturn the Examiner's final rejection of the claims.

During patent examination, the PTO bears the initial burden of presenting a prima facie case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). The Office has not met the initial burden of demonstrating unpatentability, as will be appreciated by the Board upon review of this Appeal.

### A. The Office erred in rejecting claims 67-71, 73-74, 76-80, 82-83, and 95-96 under 35 U.S.C. § 102(b) because the Zehel patent does not teach each and every element of Appellants' claimed invention.

Claim 67 is presented below:

67. An endoluminal apparatus comprising:

an elongated main body having a proximal end, a distal end, a longitudinal axis, and at least one lumen extending through the main body, the main body comprising a single tube having at least a first section near the proximal end and a second section near the distal end, and with the first section comprising a plurality of nested links with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other and having a plurality of first pullwire lumens,

a plurality of first pullwires routed through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the elongated main body at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the main body, the first pullwires being substantially symmetrically spaced around the periphery of the nested links of the first section,

a tensioning mechanism operatively coupled to each of said first pullwires and adapted to impart a tension force that is substantially evenly distributed to each of said first pullwires, wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition, and

wherein the second section is steerable relative to the first section; and

a scope extended through at least a portion of said at least one lumen, said scope being moveable through said lumen relative to said elongated main body.

Accordingly, claim 67 recites an apparatus that includes, *inter alia*,

- an elongated main body “*comprising a single tube*” with a first (proximal) section having a plurality of nested links and a second (distal) section being “*steerable relative to the first section,*”
- a tensioning mechanism for imparting a tension force on pullwires extending through the nested links of the first section to switch the first section from a flexible to a rigid condition, and
- a scope extended through a lumen in the main body and being “*movable through said lumen.*”

The Zehel patent, on the other hand, describes two embodiments of a flexible steerable exploratory device, each of which includes an elongated shaft having an inner conduit 10 and an outer conduit 11. One or both of the inner and outer conduits 10, 11 may be made rigid along its entire length. (Zehel, col. 4, ll. 4-20). In the first embodiment, shown in FIG. 1 (reproduced below), the device includes a steerable distal

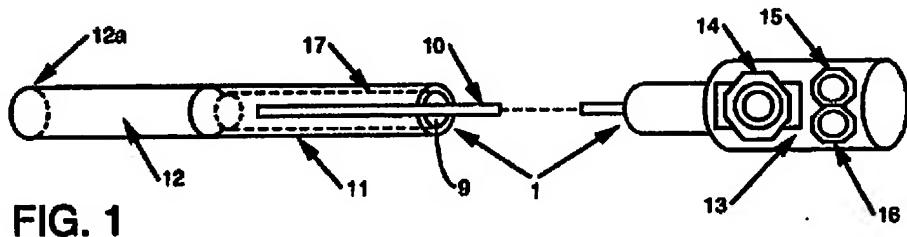


FIG. 1

end 12. (Col. 4, ll. 33-39). The distal end 12 also optionally includes one or more other instruments for conducting a variety of procedures. (Col. 5, ll. 48-58). In the second embodiment, shown in FIGS. 7-8 (reproduced below), the device does not include the steerable distal end, instead having an elastic membrane 40 enclosing the outer conduit 11 and inner conduit 10. (Col. 9, ll. 12-28). The second embodiment optionally includes “standard endoscopic devices” or their component parts occupying the center section 29 of the device, or the second embodiment “can be an add-on device for an existing endoscope.” (Col. 10, ll. 20-29).

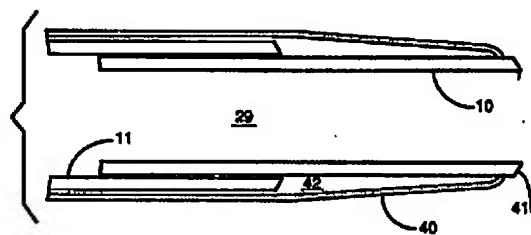


FIG. 7

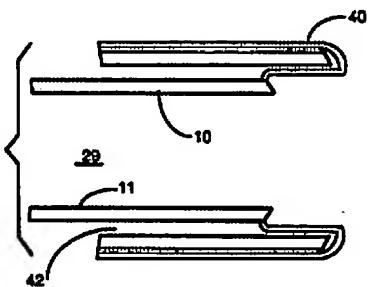


FIG. 8

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Moreover, in order to anticipate, a prior art reference must not only disclose all elements of the claim within its four corners, but it must also disclose those elements “arranged as in the claim.” See Net MoneyIn, Inc. v. Verisign, Inc., 545 F.3d 1359, 1370 (Fed. Cir. 2008).

Neither of the device embodiments disclosed in the Zehel patent is sufficient to establish a *prima facie* case of anticipation of claim 67. The first embodiment, shown in FIG. 1, does not include an elongated main body “comprising a single tube,” nor does the embodiment include “a scope extended through” the main body lumen with the scope “being movable” through the lumen. Zehel’s first embodiment includes, instead, an elongated main body made up of inner and outer conduits, and a “vision aperture” that is housed in the distal end of the main body. For at least these reasons, there can be no anticipation of claim 67 by the first embodiment device described in the Zehel patent.

The Zehel second embodiment, shown in FIGS. 7-8, also does not include an elongated main body “comprising a single tube.” Instead, the second embodiment device includes inner and outer conduits. The second embodiment also does not include a second section of the main body that is “steerable relative to the first section.” For that matter, the second Zehel embodiment also does not teach or disclose a second section of the main body that is located distally of the first section such that the pullwires are “fixed to the elongated main body at a location at or near a distal end of the first section.” For at least these reasons, there can be no anticipation of claim 67 by the Zehel second embodiment.

Significantly, even if the two Zehel embodiments were combined, the combination still would not anticipate claim 67 because each of the embodiments includes a main body having inner and outer conduits, rather than the “single tube” recited in claim 67. Combining these discrete embodiments – or isolated teachings from those embodiments – also would be improper as a basis for showing anticipation because Zehel does not disclose the elements “arranged as in the claim.” See Net MoneyIn, 545 F.3d at 1370.

Accordingly, Appellants respectfully submit that the rejections of claims 67-71, 73-74, 76-80, 82-83, and 95-96 are in error. Therefore, the rejections of those claims should be overturned by the Board.

**B. The Office erred in rejecting claims 84 and 94 under 35 U.S.C. § 103(a) because the combinations of (1) Zehel and Furihata and (2) Zehel and Boury do not teach each and every element of Appellants’ claimed invention.**

Claim 84 was rejected as being unpatentable over the combination of Zehel and Furihata, and claim 94 was rejected as being unpatentable over the combination of Zehel and Boury. Appellant traverses these rejections for the following reasons.

Claims 84 and 94 both depend from claim 67, which is patentable over Zehel for the reasons presented in Section A above. Neither of the Furihata and Boury patents corrects the deficiencies of the Zehel patent discussed above. For these reasons, there can be no prima facie case of obviousness of either of claims 84 or 94 based upon these combinations of references.

C. **The Office erred in rejecting claim 92 under 35 U.S.C. § 103(a) because the combination of Zehel and Boury do not teach each and every element of Appellants' claimed invention.**

Claim 92 is presented below:

92. Apparatus, comprising:

a shaft comprising a single tube having a first section, a second section, and a

longitudinal axis;

a plurality of first links in the first section, with adjacent first links pivotably abutting each other but not connected to each other, and with substantially each first link having a contoured front surface adapted to engage with a contoured back surface of an adjacent first link and having a plurality of first pullwire lumens;

a plurality of first pullwires extending through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the shaft at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the shaft, the first pullwires being substantially symmetrically spaced around the periphery of the first links of the first section;

a plurality of second links in the second section, with adjacent second links pivotably abutting each other but not connected to each other, and with substantially each second link having a contoured front surface adapted to engage with a contoured back surface of an adjacent second link;

at least one second section steering wire extending through substantially each of the first links and the second links; and

at least one working lumen extending through substantially each of the first links and the second links; and

a scope extended through at least a portion of said at least one working lumen, said scope being moveable through said working lumen relative to said shaft.

Accordingly, claim 92 recites an apparatus that includes, inter alia,

- a shaft "comprising a single tube" having first and second sections each made up of a plurality of links,

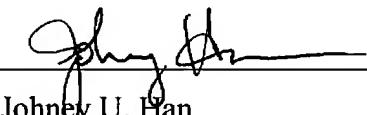
- pullwires extending through the first section and a steering wire extending through both the first and second sections,
- a working lumen extending through the shaft, and
- a scope movably extended through the working lumen.

As noted in Section A above, neither of Zehel's two disclosed embodiments includes all of the foregoing highlighted limitations from claim 92. Nor does Boury correct these deficiencies. For example, Boury does not teach a scope "extended through" a lumen in the main body, or that such a scope is "moveable through" the lumen. For at least these reasons, there can be no *prima facie* case of obviousness of claim 92.

### CONCLUSION

For at least the reasons set forth above, the claims currently pending in the application are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102(e) and 103(a) are improper and should be withdrawn. Appellants respectfully request the Board to overturn the Examiner's rejections with instructions to allow the claims.

Respectfully submitted,



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### VIII. CLAIMS APPENDIX

1-66. (Cancelled)

67. An endoluminal apparatus comprising:

an elongated main body having a proximal end, a distal end, a longitudinal axis, and at least one lumen extending through the main body, the main body comprising a single tube having at least a first section near the proximal end and a second section near the distal end, and with the first section comprising a plurality of nested links with substantially all adjacent links having mating surfaces that are in contact with but that are not connected to each other and having a plurality of first pullwire lumens,

a plurality of first pullwires routed through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the elongated main body at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the main body, the first pullwires being substantially symmetrically spaced around the periphery of the nested links of the first section,

a tensioning mechanism operatively coupled to each of said first pullwires and adapted to impart a tension force that is substantially evenly distributed to each of said first pullwires, wherein the first section may be selectively switched between a substantially flexible condition and a substantially rigid condition, and

wherein the second section is steerable relative to the first section; and

a scope extended through at least a portion of said at least one lumen, said scope being moveable through said lumen relative to said elongated main body.

68. The apparatus of claim 67 wherein the main body includes a torque transmitting feature which provides torque transmission between the proximal and distal ends while the main body is unlocked, to cause the main body to rotate substantially about its central axis.

69. The apparatus of claim 68 wherein the distal end comprises an atraumatic tip having at least one opening corresponding to the at least one lumen.

70. The apparatus of claim 67 wherein the second section may be switched between a flexible state and a substantially rigid state independently of the first section.

71. The apparatus of claim 67 with substantially each link in the first section configured to allow partial rotation relative to adjacent links and with the links arranged so that the first section can bend in at least two dimensions.

72. (Cancelled).

73. The apparatus of claim 67 wherein the second section is steerable in up to three dimensions relative to the first section.

74. The apparatus of claim 73 wherein the second section is steerable in a single dimension relative to the first section.

75. (Cancelled).

76. The apparatus of claim 67 further comprising at least two liners extending along a length of the elongated main body.

77. The apparatus of claim 76 wherein at least one liner can transmit torque.

78. The apparatus of claim 67 further comprising a liner creating a lumen in the main body.

79. The apparatus of claim 78 wherein the liner has a hydrophilic coating.

80. The apparatus of claim 67 wherein said scope comprises an endoscope extendable through the main body, with the endoscope having a steerable tip.

81. (Cancelled)

82. The apparatus of claim 67 further comprising an insuflation lumen within the main body.

83. The apparatus of claim 80 wherein a first end of the endoscope is positionable in an off-axis position relative to the elongated main body such that a region of interest spaced apart from the elongated main body may be viewed at an angle via the endoscope.

84. The apparatus of claim 67 further comprising a Y-port located along the first section, wherein the Y-port is in communication with at least one lumen extending through the elongated main body.

85-91. (Cancelled)

92. Apparatus, comprising:  
a shaft comprising a single tube having a first section, a second section, and a longitudinal axis;  
a plurality of first links in the first section, with adjacent first links pivotably abutting each other but not connected to each other, and with substantially each first link having a contoured front surface adapted to engage with a contoured back surface of an adjacent first link and having a plurality of first pullwire lumens;  
a plurality of first pullwires extending through substantially each of the first pullwire lumens, with each of the first pullwires being fixed to the shaft at a location at or near a distal end of the first section and at substantially a common point along the longitudinal axis of the shaft, the first pullwires being substantially symmetrically spaced around the periphery of the first links of the first section;  
a plurality of second links in the second section, with adjacent second links pivotably abutting each other but not connected to each other, and with substantially each second link having a contoured front surface adapted to engage with a contoured back surface of an adjacent second link;

at least one second section steering wire extending through substantially each of the first links and the second links; and

at least one working lumen extending through substantially each of the first links and the second links; and

a scope extended through at least a portion of said at least one working lumen, said scope being moveable through said working lumen relative to said shaft.

93. (Cancelled)

94. The apparatus of claim 67 with the second section comprising a plurality of links.

95. The apparatus of claim 67, wherein each of the first pullwires is fixed to one of the plurality of nested links at or near a distal end of the first section.

96. The apparatus of claim 67, wherein said tensioning mechanism comprises a pulley and wherein at least one of the first pullwires is routed through the pulley.

**IX. EVIDENCE APPENDIX**

None.

**X. RELATED PROCEEDINGS APPENDIX**

None.